

Notice of Allowability	Application No.	Applicant(s)	
	10/591,371	RUSSWURM ET AL.	
	Examiner	Art Unit	
	STEPHEN KAPUSHOC	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the interview with Applicant on 11/23/2011.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 33.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>02/24/2011</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20111123</u>. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other ____. |
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/Stephen Kapushoc/
Primary Examiner, Art Unit 1634

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Stephan Pendorf on 11/23/2011.

The application has been amended as follows:

In the Claims:

Claims 1-32. Cancelled.

Claim 33. A method for differentiating non-septic systemic inflammatory response syndrome (SIRS) from sepsis in a human subject, said method comprising:

- a. measuring the abundance of a plurality of mRNAs in a blood sample from said human subject; and
- b. comparing the abundance of the plurality of mRNAs in the blood sample from said human subject to the abundance of the plurality of mRNAs in blood samples from a control population of human subjects with non-septic SIRS;

wherein the plurality of mRNAs comprises:

- (i) mRNA, expressed from the MAGED1 gene, comprising at least 20 contiguous nucleotides of SEQ ID NO: 1;
- (ii) mRNA, expressed from the H1F2 gene, comprising at least 20 contiguous nucleotides of SEQ ID NO: 2;
- (iii) mRNA, expressed from the DEFA4 gene, comprising at least 20 contiguous nucleotides of SEQ ID NO: 3;
- (iv) mRNA, expressed from the SLC2A1 gene, comprising at least 20 contiguous nucleotides of SEQ ID NO: 4;
- (v) mRNA, expressed from the IHPK1 gene, comprising at least 20 contiguous nucleotides of SEQ ID NO: 5;
- (vi) mRNA, expressed from the IGLL1 gene, comprising at least 20 contiguous nucleotides of SEQ ID NO: 6;
- (vii) mRNA, expressed from the FLJ12085 gene, comprising at least 20 contiguous nucleotides of SEQ ID NO: 7;

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- (viii) mRNA, expressed from the CA1 gene, comprising at least 20 contiguous nucleotides of SEQ ID NO: 9;
- (ix) mRNA, expressed from the ZAP70 gene, comprising at least 20 contiguous nucleotides of SEQ ID NO: 10;
- (x) mRNA, expressed from the IGHM gene, comprising at least 20 contiguous nucleotides of SEQ ID NO: 78;
- (xi) mRNA, expressed from the KIAA0481 gene, comprising at least 20 contiguous nucleotides of SEQ ID NO: 79;
- (xii) mRNA, expressed from the IGKV1D-12 gene, comprising at least 20 contiguous nucleotides of SEQ ID NO: 81; and
- (xiii) mRNA, expressed from the KLF1 gene, comprising at least 20 contiguous nucleotides of SEQ ID NO: 87;

wherein an increased likelihood of the presence of sepsis in said human subject is determined when the abundance of the plurality of mRNAs in the blood sample from said human subject is statistically significantly greater than abundance of the plurality of mRNAs in blood samples from a control population of human subjects with non-septic SIRS.

Claims 34-38. Cancelled

2. The following is an examiner's statement of reasons for allowance:

With the amendments to the claims as set forth above, the rejections as set forth in the Office Action of 11/23/2010 and applied against claims that are now cancelled are **WITHDRAWN** in light of the cancellation of those claims. The objection to claim 33, as set forth on page 3 of the Office Action of 11/23/2010 is **WITHDRAWN** in light of the Examiner's Amendment. The prior art does not teach or suggest the differentiation between non-septic SIRS and sepsis in a methods wherein the differentiation is based on the measurement of mRNA from the thirteen genes as required in allowed claim, where such a method is taught in the instant specification.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEPHEN KAPUSHOC whose telephone number is (571)272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephen Kapushoc/
Primary Examiner, Art Unit 1634